State of Maryland
Maryland Department of Health – Laboratories Administration

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Laboratory Ethics Policy

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8/17/2017

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08/18/17

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LABORATORY ETHICS POLICY
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REVISION RECORD

Revision	Date	Changes	Made By (initials)	Effective Date
0.0	11/2012	First prepared and distributed	R. Hergenhahn	12/01/2012
1.0	10/29/2014	Added Preface, Appendix A, document control no., page numbers, and changed the date on the cover page	R. V. Michael	11/01/2014
1.1	11/23/2015	Added comments about Maryland Public Ethics Law and conflict of interest, and Appendix A	H. Peters	1/4/2016
2.1	08/02/2017	Added impartiality and confidentiality. Updated agency name according to House Bill 180. Updated website address.	H. Peters	09/04/2017

PREFACE

The scope of this policy is to establish various factors required by the management system for assuring confidence in the quality of tests performed by laboratories in the Laboratories Administration in support of regulatory and certification and accreditation requirements.

This is a policy document for the various laboratories in the Laboratories Administration for the development of their own internal quality assurance system on policies, procedures, and operation and describes the elements and functioning of that system. Generally, laboratory personnel will continue to establish and determine the means of making process improvements on a continuing basis in order to meet and exceed the needs and expectations of the customers. Laboratory personnel are generally motivated by the desire to produce consistent and accurate data that reflects the quality of laboratory services the Laboratories Administration provides in complying with the needs of its customers.

Overall, it is the intent of this policy, in concert with the standard operating procedures manual, to promote and maintain a high level of quality and excellence in the performance of various chemical analyses.

Robert A. Myers, Ph.D.
Director
Laboratories Administration

Laboratory Ethics Policy

Ethics is generally synonymous with moral philosophy or moral principles governing the appropriate conduct of a person or group. It is doing the right thing, being honest and straightforward, not lying or cheating. It is a code of conduct that includes the analysis and employment of concepts such as right and wrong, good and evil, and personal responsibility of making appropriate choices. Ethical conduct follows the code and unethical conduct does not follow the code, and when choices are made that do not follow the code, the acts are considered deliberate and intentional. In the Laboratories Administration, ethical laboratory conduct is directly related to the "conduct of a scientific or management staff in relation to data integrity".

Improper laboratory practice is defined as a scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable. Laboratory accidents or unintentional mistakes or omissions are not considered willful or intentional act to commit unethical laboratory practice. On the other hand, *Laboratory Fraud* is defined as the deliberate falsification of analytical or quality assurance results, where failed method requirements are made to appear acceptable during reporting. Laboratory Fraud is the *intentional* recording or reporting of incorrect information. It is an intentional gross deviation from method specified analytical practices, combined with the intent to conceal the deviation. Some possible legal actions for laboratory fraud include, but not limited to employee suspension, termination, and civil or criminal prosecution.

In the Laboratories Administration, *risk management* which incorporates *impartiality* and *confidentiality* are integral components of our Ethics Policy. Impartiality is the principle holding that decisions are based on objective evidence obtained during assessments, not on the basis of bias or prejudice caused by influence of different interests of individuals or other involved parties. Responsibility for ensuring impartiality of laboratory services and consultation and maintain confidentiality is the responsibility of both management and the staff. Threats to impartiality and confidentiality are usually common to all laboratory testing activities, in a few instances, cannot be eliminated, but must be managed to an acceptable level of risk. Threats of any kind must be immediately identified and effectively controlled. In order to conform to regulatory requirements and legal statutes, the Laboratories Administration evaluate risks to impartiality and confidentiality on an on-going basis. Risks to impartiality may exist based on management, personnel, shared resources, finances, or contracts.

It is the policy of the Laboratories Administration that all employees shall, at all times conduct themselves and the business of laboratory testing in an ethical manner and adhere to the fundamental principles of scientific integrity. The Laboratories Administration management and staff are committed to uncompromising, uncensored ethical standards of conduct, which can result in enhancing our reputation for quality, reliability, integrity, and responsiveness. Compliance with this policy shall be strictly enforced. Each employee of the Laboratories Administration agrees to comply with the following C*ode of Laboratory Ethics*:

- Follow all applicable established policies and procedures promulgated by the State, the MD Department of Health (MDH), and the Laboratories Administration; maintain a safe and healthy work environment, and practice professionalism, honesty and respect for others in the workplace.
- Comply with all applicable federal, State, and local laws and regulations. As a State employee, each employee should be aware of the Maryland Public Ethics Law (General Provisions Article Title 5) which include impartiality, confidentiality, and conflict of interest activities specifically at designated job levels who are required to file financial disclosure statements and adhere to the Standards of Conduct that apply to all employees within Maryland State government.
- Implement and comply with written risk policies and procedures to minimize threats to impartiality and confidentiality; document training and acknowledgement by management and staff on potential threats to impartiality and confidentiality, and approve policies and procedures intended to minimize these threats. Threats to impartiality are permanently identified, reviewed and controlled for safeguarding impartiality.
- Generate and report test data that is accurate, precise, and of known and documented quality.
- Implement best laboratory practices based on the principles of ISO 17025 (or other accrediting agencies) about pre-analytical, analytical, and post-analytical protocols and procedures.
- Seek opportunities for training and education to develop competence and skills in performance of professional duties.
- Conduct laboratory tests with the awareness of how the results affect public health programs and decisions.
- Maintain high standards of honesty, integrity, and diligence in the performance of testing, training, research, and all other professional duties
- Assure that tests are performed with the highest technical competency by adhering to standard operating procedures, quality control protocols, regulatory requirements, and the Administration's training guidelines.

- Create and maintain a culture of competence, character, respect, trust and integrity that will nurture long-term partnerships with co-workers, and internal and external customers.
- Create, promote, and maintain a culture that respects and perpetuates novel ideas, corrective actions, teamwork, and continuous quality improvement.
- Recognize overall analytical laboratory performance is ultimately measured by our ability not merely to meet expectations, but to exceed them.
- Participate in annual training on practical ethics policy and Conflict of Interest for all staff in the Laboratories Administration and remain knowledgeable about this subject matter.
- Understand management's position of '*zero tolerance*' regarding employees being subject to inappropriate pressures, laboratory dilemmas, coercion, intimidation, or bribery to falsify, short-cut, camouflage, conceal or misrepresent facts about a test procedure, test results, or data management, or otherwise engage in bad laboratory practices.
- Promote and maintain effective bi-lateral communication through the chain-of-command regarding concerns, inquiries, or allegations pertaining to suspected unethical conduct, questionable practices, observing key warning signs, or when in doubt to ask questions.
- Understand the serious implications and consequences of unethical conduct in any testing activity, intent to defraud, or any perception of impropriety.
- Refer to MDH – Laboratories Administration, "*Non-Retaliation Policy for Reporting Problems of Quality, Safety and Security*", which is incorporated by reference and included as Appendix A.

LABORATORIES ADMINISTRATION

ACKNOWLEDGEMENT

I hereby certify that I have read, understand, and will comply and adhere with the Laboratories Administration "Laboratory Ethics Policy".

Print Name / Signature

Date

APPENDIX A

MARYLAND
Department of Health
Larry Hogan, Governor · Boyd Rutherford, Lt. Governor · Dennis Schrader, Secretary

Laboratories Administration
Robert A. Myers, Ph.D., Director

MDH Laboratories Administration
Version Effective September 1, 2017

NON-RETALIATION POLICY for REPORTING PROBLEMS of QUALITY, SAFETY and SECURITY

I. INTRODUCTION

As described in this Non-Retaliation Policy, an employee who reports problems of quality, safety or security will be protected from any form of retaliation. Problems may include, but are not limited to, safety violations or potential hazards, CLIA, EPA or FDA compliance deviations or deficiencies, client complaints, and unsafe conditions.

II. PURPOSE

The Laboratories Administration (Administration) is committed to maintaining the highest level of professional and ethical standards in delivering quality services to the citizens of Maryland. To ensure that these standards are achieved and sustained, the Administration wishes to foster an environment in which all employees and other persons feel free to report quality, safety and security problems.

III. APPLICABILITY

This Policy makes quality, safety and security problem reporting mandatory for all Administration employees including staff, supervisors and management. It requires management to receive and respond to reports, and protects those who make appropriate reports in good faith. It requires all Administration employees to cooperate with problem investigation efforts.

IV. POLICY

A. GENERAL

The Administration is committed to investigating all reported concerns promptly and, to the extent reasonable, confidentially. No one in the Administration will retaliate through any form of harassment, intimidation, denial of promotion or raises, loss of employment, denial of continuing education opportunities, threats, coercion, discrimination, or any other form of

retaliatory action against employees, or other persons for:

1.0 Exercising any right under, or participating in any process established by federal, State, or local law or regulations or Administration policies;

2.0 Identifying, reporting and/or documenting a quality, safety or security problem within the Administration;

3.0 Admitting mistakes and/or errors;

4.0 Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing; or

5.0 Opposing in good faith any act, practice, or procedure that is unlawful by federal, state, or local law or regulation or that is improper according to the Administration's policies or procedures.

B. SCOPE

The applicable laws and regulations covered by this Policy include those the Administration must adhere to in its function as a public health and medical laboratory. Examples include: Clinical Laboratory Improvement Amendments of 1988 (CLIA); Occupational Safety and Health Act; Health Insurance Portability and Accountability Act; Health-General Article, Title 17, Laboratories, Annotated Code of Maryland; Code of Maryland Regulations (COMAR) 10.10.01-.10 ; and the CLIA rules in the Code of Federal Regulations Title 42, Part 493.

This Policy supplements and does not replace the MDH Corporate Compliance Program Code of Conduct, the State Personnel and Pensions Article or any of the Administration's policies and procedures.

C. EMPLOYEE RESPONSIBILITIES

All employees must help create a culture within the Administration that promotes the highest standards of compliance, and everyone in the Administration is encouraged to address problems when they arise. All Administration employees have an obligation to familiarize themselves with, and adhere to all applicable federal and State laws and regulations that apply to quality, safety and security for public health laboratories. Where any question or uncertainty regarding these standards exists, each affected employee is required to seek guidance from his or her supervisor, Division Chief, the Safety and Security Officer, the Quality Assurance Officer, a Deputy Director, or the Director.

All employees are obligated to identify, report and document quality, safety and security problems. It is the responsibility of all employees of the Administration to report an activity by an employee, contractor, or vendor that the employee has reason to believe violates applicable laws, rules, regulations, this Policy, the MDH Corporate Compliance Program Code of Conduct, and/or the Administration's policies and procedures. This includes actual or potential problems. An employee may report problems to his or her supervisor, Regional Laboratory Chief or Director, Division Chief, the Safety and Security Officer, the Quality Assurance Officer, a Deputy Director, or the Director. Employees may also use the confidential reporting mechanism as set forth in the MDH Corporate Compliance Plan.

Adherence to this Policy and participation in related activities and training will be an important factor in evaluating an employee's performance.

D. MANAGEMENT RESPONSIBILITIES

While all Administration employees are obligated to follow this Policy, management will

provide access to the information, training and resources needed by employees to comply with applicable federal, State or local laws or regulations, and Administration policies and procedures. For the purposes of this Policy, management includes anyone with supervisory responsibilities or individuals designated by the Director including the Quality Assurance Officer, the Safety and Security Officer, the Regional Lab Chiefs and Directors, the Division Chiefs, and the Deputy Directors.

All management employees shall maintain an "open-door policy" to encourage employees, contractors, vendors, clients, and other persons to report quality, safety and security problems. A management employee who receives a problem report is obligated to investigate it personally or assign it to a designee and forward the report to the Quality Assurance Officer.

E. QUALITY ASSESSMENT: MONITORING AND DOCUMENTATION

Policy oversight is an important element in the evaluation of the Administration's management employees. All investigations will be documented and routinely reviewed as part of the Administration's Quality Assessment Program.

F. REPORTS MUST BE IN GOOD FAITH AND REASONABLE

This Policy applies to all quality, safety and security problem reports that are made in good faith and that are expressed in a manner that is reasonable and that does not violate the law. An employee who makes a quality, safety or security problem report that they know to be false or misleading will be subject to progressive discipline.

G. CORRECTIVE REMEDIAL ACTION

When an investigation identifies a deficiency or a violation from a reported problem, it is the policy of the Administration to initiate appropriate corrective remedial action and to implement system changes to prevent a similar problem from recurring in the future.

H. DISCIPLINARY ACTION

An Administration employee, including all levels of supervision and management, who violates this Policy, will be subject to progressive discipline.

I. ACKNOWLEDGMENT PROCESS

Following training on this Policy or orientation as a new employee, Administration employees will be required to sign a "Policy Acknowledgement Statement" confirming: receipt of this Policy; understanding the obligations and principles of this Policy; recognizing the consequences of breaching this Policy; and agreeing to comply with this Policy as a condition of employment.

Approved: Robert A. Myers, Ph.D., Director — Date: 08/18/17

APPENDIX A

NON-RETALIATION POLICY FOR REPORTING PROBLEMS OF QUALITY, SAFETY, AND SECURITY

POLICY ACKNOWLEDGMENT STATEMENT

I hereby acknowledge that I have received the MH Laboratories Administration's Non-Retaliation Policy for Reporting Problems of Quality, Safety and Security, and I fully understand that I have an obligation to adhere to the principles of this Policy and recognize the consequences that may occur should I breach this Policy, and that I consent to comply with this Policy.

(This Acknowledgement Statement will be kept in the employee's Personnel File)

EMPLOYEE SIGNATURE_____ DATE_____

PRINTED NAME (Last, First, Middle)_____

ORGANIZATIONAL UNIT_____

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